One of the first initiatives undertaken by the newly organized American Cochlear Implant Alliance was the formation of a multi-center study to explore outcomes in older adults with greater speech recognition than is allowed under current Medicare coverage criteria. We approached the Centers for Medicare and Medicaid Services (CMS), requesting that they partner with us and allow Medicare expanded coverage for individuals who were part of the ACI Alliance study. Principal investigators Terry Zwolan PhD, Craig Buchman MD, and John Niparko MD led the study effort.

The study assessed outcomes in Medicare beneficiaries with scores that fell between 40 and 60% correct on AzBio sentences in the best aided condition when stimuli were presented in quiet at 60 dBA. Study results were published in *JAMA Otolaryngology* in October 2020 “Assessment of Cochlear Implants for Adult Medicare Beneficiaries Aged 65 Years or Older Who Meet Expanded Indications of Open-Set Sentence Recognition” by Zwolan et al.

Coverage Determination Process Announced March 1

The study results were favorable and helped us in our efforts to formally request a reconsideration of criteria under a formal process through CMS called a National Coverage Determination (NCD). The NCD request was opened for public comment on March 1.

ACI Alliance provided guidance to our members and others in the broad hearing loss community to encourage as much input and support as possible. When the comment period closed on March 31, 32 comments had been submitted by our associated organizations including the American Academy of Audiology, ASHA, Academy of Dispensing Audiologists, AAO-HNS and the ITEM Coalition. Dozens of our members documented their experiences as CI clinicians and researchers, and the need to provide older adults with candidacy criteria that more closely matched that of individuals covered by private insurance. Three hearing implant companies submitted comments based on data that they have collected on patient outcomes. Adult CI recipients, many of whom are active in ACI Alliance submitted comments, adding their important perspective. Formal comments submitted by ACI Alliance are posted on our website as are the comments of PIs Drs. Terry Zwolan and Craig Buchman.

The full set of public comments are available online here.

Lou Ferrigno Shares His Personal Story with CMS

On April 5, ACI Alliance met with CMS officials responsible for evaluating the NCD and determining how and whether CI candidacy will be changed. We brought with us *The Incredible Hulk* to share his compelling journey with hearing loss and then, recently receiving a cochlear implant. Lou noted that his hearing had declined in recent years, making it increasingly difficult to interact with the range of people in his personal and professional life. Since he received a cochlear implant a year ago, his hearing has dramatically improved and he urged CMS officials to make CIs more readily available to those older adults who may benefit. We were all moved by his compelling story as well as his interest in helping ACI Alliance with this important public policy goal.

What Happens Next?

CMS will review the submitted comments and compare them to the proposed expanded coverage criteria to determine if the comments support the proposal. CMS will then publish a summary of the public comments received and responses to the comments. Based upon the analysis of the evidence base and the public comments, CMS will issue a preliminary coverage determination that is responsive to the NCD request. That preliminary determination will again be subject to public comment and, after another 30-day comment period, CMS will make a final decision. That decision will become the new and updated NCD for CI coverage for Medicare beneficiaries. ACI Alliance will continue to monitor the process and seek the input and involvement of our members and the entire hearing health community as the process moves forward.

Lou Ferrigno joined ACI Alliance representatives Donna Sorkin, Peter Thomas (Powers Pyles Sutter & Verville PC) and Terry Zwolan (Hearing First) at the virtual meeting with CMS on the NCD.